



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

[Docket Number: OIG-1302-N]

Special Fraud Alert: Physician-Owned Entities

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: This Special Fraud Alert addresses physician-owned entities that derive revenue from selling, or arranging for the sale of, implantable medical devices ordered by their physician-owners for use in procedures the physician-owners perform on their own patients at hospitals or ambulatory surgical centers (ASCs).

DATES: These regulations are effective on **[insert date of publication in the Federal Register]**.

FOR FURTHER INFORMATION CONTACT: Patrice S. Drew, Department of Health and Human Services, Office of Inspector General, Congressional and Regulatory Affairs, at (202) 619-1368.

I. Introduction

 This Special Fraud Alert addresses physician-owned entities that derive revenue from selling, or arranging for the sale of, implantable medical devices ordered by their physician-owners for use in procedures the physician-owners perform on their own patients at hospitals or ambulatory surgical centers (ASCs).

These entities frequently are referred to as physician-owned distributorships, or "PODs."¹ The Office of Inspector General (OIG) has issued a number of guidance documents on the general subject of physician investments in entities to which they refer, including the 1989 Special Fraud Alert on Joint Venture Arrangements² and various other publications. OIG also provided guidance specifically addressing physician investments in medical device manufacturers and distributors in an October 6, 2006 letter.³ In that letter, we noted "the strong potential for improper inducements between and among the physician investors, the entities, device vendors, and device purchasers" and stated that such ventures "should be closely scrutinized under the fraud and abuse laws."⁴ This Special Fraud Alert focuses on the specific attributes and practices of PODs that we believe

¹ The physician-owned entities addressed in this Special Fraud Alert are sometimes referred to as "physician-owned companies" or by other terminology. For purposes of this Special Fraud Alert, a "POD" is any physician-owned entity that derives revenue from selling, or arranging for the sale of, implantable medical devices and includes physician-owned entities that purport to design or manufacture, typically under contractual arrangements, their own medical devices or instrumentation. Although this Special Fraud Alert focuses on PODs that derive revenue from selling, or arranging for the sale of, implantable medical devices, the same principles would apply when evaluating arrangements involving other types of physician-owned entities.

² Special Fraud Alert: Joint Venture Arrangements (August 1989), reprinted at 59 Fed. Reg. 65,372, 65,374 (Dec. 19, 1994).

³ Letter from Vicki Robinson, Chief, Industry Guidance Branch, Department of Health and Human Services, OIG, Response to Request for Guidance Regarding Certain Physician Investments in the Medical Device Industries (Oct. 6, 2006).

⁴ Id.

produce substantial fraud and abuse risk and pose dangers to patient safety.

II. The Anti-Kickback Statute

One purpose of the anti-kickback statute is to protect patients from inappropriate medical referrals or recommendations by health care professionals who may be unduly influenced by financial incentives. Section 1128B(b) of the Social Security Act (the Act) makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce, or in return for, referrals of items or services reimbursable by a Federal health care program. When remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. Violation of the statute constitutes a felony punishable by a maximum fine of \$25,000, imprisonment up to 5 years, or both. Conviction will also lead to exclusion from Federal health care programs, including Medicare and Medicaid. OIG may also initiate administrative proceedings to exclude persons from the Federal health care programs or to impose civil money penalties for

fraud, kickbacks, and other prohibited activities under sections 1128(b)(7) and 1128A(a)(7) of the Act.

III. Physician-Owned Distributorships

Longstanding OIG guidance makes clear that the opportunity for a referring physician to earn a profit, including through an investment in an entity for which he or she generates business, could constitute illegal remuneration under the anti-kickback statute. The anti-kickback statute is violated if even one purpose of the remuneration is to induce such referrals.

OIG has repeatedly expressed concerns about arrangements that exhibit questionable features with regard to the selection and retention of investors, the solicitation of capital contributions, and the distribution of profits. Such questionable features may include, but are not limited to: (1) selecting investors because they are in a position to generate substantial business for the entity, (2) requiring investors who cease practicing in the service area to divest their ownership interests, and (3) distributing extraordinary returns on investment compared to the level of risk involved.

PODs that exhibit any of these or other questionable features potentially raise four major concerns typically associated with kickbacks—corruption of medical judgment, overutilization, increased costs to the Federal health care

programs and beneficiaries, and unfair competition. This is because the financial incentives PODs offer to their physician-owners may induce the physicians both to perform more procedures (or more extensive procedures) than are medically necessary and to use the devices the PODs sell in lieu of other, potentially more clinically appropriate, devices. We are particularly concerned about the presence of such financial incentives in the implantable medical device context because such devices typically are "physician preference items," meaning that both the choice of brand and the type of device may be made or strongly influenced by the physician, rather than being controlled by the hospital or ASC where the procedure is performed.

We do not believe that disclosure to a patient of the physician's financial interest in a POD is sufficient to address these concerns. As we noted in the preamble to the final regulation for the safe harbor relating to ASCs:

...disclosure in and of itself does not provide sufficient assurance against fraud and abuse...[because] disclosure of financial interest is often part of a testimonial, i.e., a reason why the patient should patronize that facility. Thus, often patients are not put on guard against the potential conflict of

interest, i.e., the possible effect of financial considerations on the physician's medical judgment.

See 64 Fed. Reg. 63,518, 63,536 (Nov. 19, 1999). Although these statements were made with respect to ASCs, the same principles apply in the POD context.

OIG recognizes that the lawfulness of any particular POD under the anti-kickback statute depends on the intent of the parties. Such intent may be evidenced by a POD's characteristics, including the details of its legal structure; its operational safeguards; and the actual conduct of its investors, management entities, suppliers, and customers during the implementation phase and ongoing operations. Nonetheless, we believe that PODs are inherently suspect under the anti-kickback statute. We are particularly concerned when PODs, or their physician-owners, exhibit any of the following suspect characteristics:

- The size of the investment offered to each physician varies with the expected or actual volume or value of devices used by the physician.
- Distributions are not made in proportion to ownership interest, or physician-owners pay different prices for their ownership interests, because of the expected or actual volume or value of devices used by the physicians.

- Physician-owners condition their referrals to hospitals or ASCs on their purchase of the POD's devices through coercion or promises, for example, by stating or implying they will perform surgeries or refer patients elsewhere if a hospital or an ASC does not purchase devices from the POD, by promising or implying they will move surgeries to the hospital or ASC if it purchases devices from the POD, or by requiring a hospital or an ASC to enter into an exclusive purchase arrangement with the POD.
- Physician-owners are required, pressured, or actively encouraged to refer, recommend, or arrange for the purchase of the devices sold by the POD or, conversely, are threatened with, or experience, negative repercussions (e.g., decreased distributions, required divestiture) for failing to use the POD's devices for their patients.
- The POD retains the right to repurchase a physician-owner's interest for the physician's failure or inability (through relocation, retirement, or otherwise) to refer, recommend, or arrange for the purchase of the POD's devices.
- The POD is a shell entity that does not conduct appropriate product evaluations, maintain or manage sufficient inventory in its own facility, or employ or otherwise contract with personnel necessary for operations.

- The POD does not maintain continuous oversight of all distribution functions.
- When a hospital or an ASC requires physicians to disclose conflicts of interest, the POD's physician-owners either fail to inform the hospital or ASC of, or actively conceal through misrepresentations, their ownership interest in the POD.

These criteria are not intended to serve as a blueprint for how to structure a lawful POD, as an arrangement may not exhibit any of the above suspect characteristics and yet still be found to be unlawful. Other characteristics not listed above may increase the risk of fraud and abuse associated with a particular POD or provide evidence of unlawful intent. For example, a POD that exclusively serves its physician-owners' patient base poses a higher risk of fraud and abuse than a POD that sells to hospitals and ASCs on the basis of referrals from nonowner physicians.

The anti-kickback statute is not a prohibition on the generation of profits; however, PODs that generate disproportionately high rates of return for physician-owners may trigger heightened scrutiny. Because the investment risk associated with PODs is often minimal, a high rate of return increases both the likelihood that one purpose of the

arrangement is to enable the physician-owners to profit from their ability to dictate the implantable devices to be purchased for their patients and the potential that the physician-owner's medical judgment will be distorted by financial incentives. Our concerns are magnified in cases when the physician-owners: (1) are few in number, such that the volume or value of a particular physician-owner's recommendations or referrals closely correlates to that physician-owner's return on investment, or (2) alter their medical practice after or shortly before investing in the POD (for example, by performing more surgeries, or more extensive surgeries, or by switching to using their PODs' devices on an exclusive, or nearly exclusive basis).

We are aware that some PODs purport to design or manufacture their own devices. OIG does not wish to discourage innovation; however, claims—particularly unsubstantiated claims—by physician-owners regarding the superiority of devices designed or manufactured by their PODs do not disprove unlawful intent. The risk of fraud and abuse is particularly high in circumstances when such physicians-owners are the sole (or nearly the sole) users of the devices sold or manufactured by their PODs.

Finally, because the anti-kickback statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction, hospitals and ASCs that enter into

arrangements with PODs also may be at risk under the statute. In evaluating these arrangements, OIG will consider whether one purpose underlying a hospital's or an ASC's decision to purchase devices from a POD is to maintain or secure referrals from the POD's physician-owners.

IV. Conclusion

OIG is concerned about the proliferation of PODs. This Special Fraud Alert reiterates our longstanding position that the opportunity for a referring physician to earn a profit, including through an investment in an entity for which he or she generates business, could constitute illegal remuneration under the anti-kickback statute. OIG views PODs as inherently suspect under the anti-kickback statute. Should a POD, or an actual or potential physician-owner, continue to have questions about the structure of a particular POD arrangement, the OIG Advisory Opinion process remains available. Information about the process may be found at: <http://oig.hhs.gov/faqs/advisory-opinions-faq.asp>.

To report suspected fraud involving physician-owned entities, contact the OIG Hotline at <http://oig.hhs.gov/fraud/report-fraud/index.asp> or by phone at 1-800-447-8477 (1-800-HHS-TIPS).

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Daniel R. Levinson

Inspector General

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